

this section do not exist or have been waived.

[48 FR 52033, Nov. 16, 1983; 48 FR 54336, Dec. 2, 1983]

#### § 184.1537 Nickel.

(a) Elemental nickel (CAS Reg. No. 7440-02-0) is obtained from nickel ore by transforming it to nickel sulfide ( $\text{Ni}_3\text{S}_2$ ). The sulfide is roasted in air to give nickel oxide ( $\text{NiO}$ ). The oxide is then reduced with carbon to give elemental nickel.

(b) The Food and Drug Administration is developing food-grade specifications for nickel in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a catalyst as defined in § 170.3(o)(24) of this chapter.

(2) The ingredient is used in the hydrogenation of fats and oils as defined in § 170.3(n)(12) of this chapter at levels not to exceed current good manufacturing practice. Current good manufacturing practice includes the removal of nickel from fats and oils following hydrogenation.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51618, Nov. 10, 1983]

#### § 184.1538 Nisin preparation.

(a) Nisin preparation is derived from pure culture fermentations of certain strains of *Streptococcus lactis* Lancefield Group N. Nisin preparation contains nisin (CAS Reg. No. 1414-45-5), a group of related peptides with antibiotic activity.

(b) The ingredient is a concentrate or dry material that meets the specifications that follow when it is tested as described in "Specifications for Identity and Purity of Some Antibiotics,"

World Health Organization, FAO Nutrition Meeting Report Series, No. 45A, 1969, which is incorporated by reference. Copies are available from the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(1) Nisin content, not less than 900 international units per milligram.

(2) Arsenic, not more than 1 part per million.

(3) Lead, not more than 2 parts per million.

(4) Zinc, not more than 25 parts per million.

(5) Copper, zinc plus copper not more than 50 parts per million.

(6) Total plate count, not more than 10 per gram.

(7) *Escherichia coli*, absent in 10 grams.

(8) *Salmonella*, absent in 10 grams.

(9) Coagulase positive staphylococci, absent in 10 grams.

(c) The ingredient is used as an antimicrobial agent as defined in § 170.3(o)(2) of this chapter to inhibit the outgrowth of *Clostridium botulinum* spores and toxin formation in pasteurized cheese spreads and pasteurized process cheese spreads listed in § 133.175; pasteurized cheese spread with fruits, vegetables, or meats as defined in § 133.176; pasteurized process cheese spread as defined in § 133.179; pasteurized process cheese spread with fruits, vegetables, or meats as defined in § 133.180 of this chapter.

(d) The ingredient is used at levels not to exceed good manufacturing practice in accordance with § 184.1(b)(1) of this chapter. The current good manufacturing practice level is the quantity of the ingredient that delivers a maximum of 250 parts per million of nisin in the finished product as determined by the British Standards Institution Methods, "Methods for the Estimation and Differentiation of Nisin in Processed Cheese," BS 4020 (1974), which is incorporated by reference. Copies are available from the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD

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20857, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

[53 FR 11250, Apr. 6, 1988, as amended at 59 FR 14364, Mar. 28, 1994]

### § 184.1540 Nitrogen.

(a) Nitrogen (empirical formula  $N_2$ , CAS Reg. No. 7727-37-9) is a colorless, odorless, flavorless gas that is produced commercially by the fractionation of liquid air.

(b) The Food and Drug Administration is developing food-grade specifications for nitrogen in cooperation with the National Academy of Sciences. In the interim, the ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitations other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a propellant, aerating agent, and gas as defined in § 170.3(o)(25) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 57270, Dec. 29, 1983]

### § 184.1545 Nitrous oxide.

(a) Nitrous oxide (empirical formula  $N_2O$ , CAS Reg. No. 10024-97-2) is also known as dinitrogen monoxide or laughing gas. It is a colorless gas, about 50 percent heavier than air, with a slightly sweet smell. It does not burn but will support combustion. Nitrous oxide is manufactured by the thermal decomposition of ammonium nitrate. Higher oxides of nitrogen are removed by passing the dry gas through a series of scrubbing towers.

(b) The Food and Drug Administration is developing food-grade specifications for nitrous oxide in cooperation with the National Academy of Sciences. In the interim, the ingredient

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must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitations other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a propellant, aerating agent, and gas as defined in § 170.3(o)(25) of this chapter.

(2) The ingredient is used in dairy product analogs as defined in § 170.3(n)(10) of this chapter at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 57270, Dec. 29, 1983]

### § 184.1553 Peptones.

(a) Peptones are a variable mixture of polypeptides, oligopeptides, and amino acids that are produced by partial hydrolysis of casein, animal tissue, soy protein isolate, gelatin, defatted fatty tissue, egg albumin, or lactalbumin (whey protein). Peptones are produced from these proteins using proteolytic enzymes that either are considered to be generally recognized as safe (GRAS) or are regulated as food additives. Peptones are also produced by denaturing any of the proteins listed in this paragraph with safe and suitable acids or heat.

(b) FDA is developing food-grade specifications for peptones in cooperation with the National Academy of Sciences. In the interim, these ingredients must be of a purity suitable for their intended use.

(c) In accordance with § 184.1(b)(1), these ingredients are used in food with no limitation other than current good manufacturing practice. The affirmation of these ingredients as GRAS as direct human food ingredients is based upon the following current good manufacturing practice conditions of use:

(1) These ingredients are used as nutrient supplements as defined in § 170.3(o)(20) of this chapter; as processing aids as defined in § 170.3(o)(24) of